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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/808,877

03/14/2001

William A. McMillan

22660-0025 DIV 3

6609

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7590

05/07/2003

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EXAMINER

TUNG, JOYCE

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 05/07/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/808,877

Applicant(s)

McMillan et al.

Examiner

Joyce Tung

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 16, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-57 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 6) ☐ Other:

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DETAILED ACTION

Interference

1. When the effective filing date of an application is more than three months after the effective filing date of a patent, under 37 CFR 1.608, an applicant seeking to provoke an interference with a patent is required to submit evidence which demonstrates that the applicant is *prima facie* entitled to a judgment relative to the patentee. The evidence may relate to patentability and need not be restricted to priority, but if the evidence shows that the claims of the application are not patentable, the claims in the application will be rejected. The applicant can file a request for reexamination of the patent, if applicable.

The evidence can be patents, publications and other documents, and one or more affidavits or declarations which demonstrate that applicant is *prima facie* entitled to a judgment relative to the patentee.

The applicants also must file an explanation stating with particularity the basis upon which the applicant is *prima facie* entitled to the judgment (See MPEP 2308).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 45-48, 50-52, and 54-57 are rejected under 35 U.S.C. 102(e) as anticipated by Wittwer et al. (6,303,305).

Wittwer et al. disclose a method for the quantification of a nucleic acid, wherein in a first step, the nucleic acid is amplified by an amplifying agent. Subsequently, first, second or n th order derivatives is calculated. The obtained value can be used to calculate the initial concentration of the analyte (See the Abstract and column 2, lines 31-39). The amount of amplification product is then determined as a function reaction time (See column 2, lines 39-42). The maximum value of the derivative is determined and the initial concentration of the analyte is calculated (See column 2, lines 43-45). By using appropriate mathematical algorithms, the generated data can be used to set up a mathematical function at different time points in which a polynomial fit is performed (See column 3, lines 29-37). The amplification is obtained exponentially at the very beginning of the reaction (See column 3, lines 53-55). The amplification product is detected by means of fluorescence (See column 4, lines 41-43). The amplification products are also detected by using two polynucleotide probes which are each labeled with a fluorescent entity and then fluorescence resonance energy transfer can take place (See column 4, lines 51-56).

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Since the limitations of claims 45-48, 50-52, and 54-57 read on the teachings of Wittwer et al. the teachings of Wittwer et al. anticipate the limitations of claims 45-48, 50-52, and 54-57.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 49 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wittwer et al. (6,303,305) as applied to claims 45-48, 50-52, and 54-57 above, and further in view of Mullis et al. (4,965,188).

The teachings of Wittwer et al. are set forth in section 3 above.

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Wittwer et al. do not disclose using intercalating dye which is ethidium bromide to detect amplified nucleic acid products

Mullis et al. disclose an amplification method in which DNA stain such as ethidium bromide can be used to diagnose DNA directly (See column 25, lines 56-60).

One of ordinary skill in the art at the time the invention was made would have been motivated to apply the intercalating dye, ethidium bromide to the method of Wittwer et al. to detect amplified nucleic acid products in order to carry out the method of quantification of the concentration of a nucleic acid in a sample. Mullis et al. states that the method is for amplifying desired nucleic acid sequence and the amplified sequence is ready to be detected (See the Abstract). It would have been prima facie obvious to apply the intercalating dye, ethidium bromide to the method of Wittwer et al in order to carry out the method for quantification of the concentration of nucleic acid in a sample.

Drawings

6. The drawings are approved.

Summary

7. No claims are allowed.

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Information Disclosure Statement

8. The references, B1 and C1 lined through were not considered because the references were not supplied. The parent application was not ordered.


9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung
J.T.
April 29, 2003


GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600